



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/463,024

02/15/2002

G. Ganga Raju

IHEAL-01063US1

5778

23910

7590

08/04/2006

FLIESLER MEYER, LLP
FOUR EMBARCADERO CENTER
SUITE 400
SAN FRANCISCO, CA 94111

EXAMINER

VANIK, DAVID L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,024

Applicant(s)

RAJU, G. GANGA

Examiner

David L. Vanik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/26/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the Applicant's Information Disclosure Statement, Amended Claims, and Remarks filed on 5/26/2006.

As a result of Applicant's amended claims, the claim objections are hereby **withdrawn**. Additionally, as a result of Applicant's amended specification, the 35 USC §112 rejections over 26-30, 40-43 are hereby **withdrawn**. It should be noted that the examiner has ordered a copy of Finish Patent 965251 from the STIC research library. Upon delivery of the Finish patent (6-8 weeks), FI 965251 will be submitted for translation and the priority date and applicability of said reference will be determined in the next office action. For now, however, the 35 USC §103 rejections over US Patent 5,536,516 ('516) in view of in view of WO 98/28989 ('989) are hereby **withdrawn**.

Both the 35 USC §112 rejections over claims 26-27 and the 35 USC §103 rejections over US 5,612,039 in view of Clouatre et al ("The Diet and Health Benefits of HCA"), in part, are hereby **maintained**.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 112

Art Unit: 1615

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 25 recites the limitation "14-26% by weight of calcium; 24-40% by weight of potassium, and 14-24% by weight of sodium." Claims 26-27 appear to be dependent of claim 25, but have calcium, potassium, and sodium ranges outside of the instant claim 25. As such, there is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Applicant's arguments filed on 5/26/2006 have been fully considered but they are not persuasive. In response to the 3/3/2006 Non-Final Rejection, Applicant asserts that the instant claims 26-27 are properly dependent on 25 and the range of calcium, potassium, and sodium are well within the range of the instant claim 25. In making this assertion, Applicant has pointed out the percentage of cations in claim 25 is based on the "total hydroxycitric acid content" while the range of cations in 26-27 is based on the "total weight" of the composition.

The above assertion has been carefully considered. However, the examiner still maintains the position that the above rejection is proper. For example, consider the situation where the total hydroxycitric acid content in claim 25 is 40% by weight. In such a situation, the composition would comprise approximately 5.6 – 10.4 % by weight of calcium, approximately 9.6 – 16% of

Art Unit: 1615

potassium by weight, or approximately 5.6 – 9.6% by weight of sodium on the basis of total weight of the composition. The above ranges are more narrow than the ones presented in the instant claims 26 – 27. Thus, the examiner respectfully submits that the rejection is proper.

Claims 28, 31-34, 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,612,039 ('039) in view of Clouatre et al ("The Diet and Health Benefits of HCA").

'039 teach a dietary supplementation composition comprising the calcium salt of Garcinia Cambogia-hydroxycitric acid extract (column 3, lines 5-14 and column 5, line 60 – column 6, line 29). According to '039, the Garcinia extract can be used to reduce appetite and assist in dietary control (column 3, lines 12-14 and column 5, lines 66-67). In terms of the dosage amount, about 750 mg may be administered to an individual prior to a meal (Claims 3-4). Since the compositions can be administered to an individual prior to breakfast, lunch, and dinner, it is the examiner's position that the compositions can be administered to an individual up to three times per day (Claims 3-5).

Although '039 teaches a hydroxycitric acid-based composition comprising calcium, it does not teach adding potassium to the weight loss composition.

Art Unit: 1615

Clouatre et al. ("The Diet and Health Benefits of HCA") suggest that potassium may augment the weight loss response of hydroxycitric acid (page 41). That is, it may be advantageous to combine potassium with hydroxycitric acid because such a combination could improve the weight loss capacity of hydroxycitric acid. Because, according to Clouatre et al, the addition of potassium to a composition can augment the weight loss effects of hydroxycitric acid, one of ordinary skill in the art would have been motivated to add potassium to the hydroxycitric acid-based composition advanced by '039. Based on the teachings of '039 together with Clouatre et al., there is a reasonable expectation that a composition comprising potassium, calcium, and hydroxycitric acid would be an effective weight loss composition. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add potassium to the calcium/hydroxycitric acid-based composition advanced by '039 in view of the teachings of Clouatre et al.

Response to Arguments

Applicant's arguments filed on 5/26/2006 have been fully considered but they are not persuasive. In response to the 3/3/2006 Non-Final Rejection, Applicant asserts that there is no motivation to combine '039 with Clouatre et al. and add potassium to the weight-loss composition advanced by '039. In making this assertion, the Applicant argues that Clouatre et al. only teaches exchanging

Art Unit: 1615

the free acid form of hydroxycitric acid with a single salt. After carefully considering this assertion, the examiner respectfully disagrees with Applicant.

As set forth on page 41 of Clouatre et al., potassium can augment weight loss effects as well as increasing thermogenesis. There is nothing on page 41 that suggests that only one salt should be added to a hydroxycitric acid-based composition. In contrast, Clouatre et al. notes that a combination of two cations, magnesium and potassium, has been shown to increase thermogenesis (page 41, lines 27 – 30). As such, the examiner respectfully asserts that there is motivation to add potassium to the calcium/hydroxycitric acid-based composition advanced by '039 (column 6, lines 5 – 28). As set forth above, there is a reasonable expectation that a composition comprising potassium, calcium, and hydroxycitric acid would be an effective weight loss composition. Additionally, a secondary motivation to add potassium to the composition advanced by '039 comes from the discovery that potassium has been shown to increase thermogenesis. Thus, the examiner respectfully submits that the rejection is proper.

In terms of the solubility, odor, and taste of the '039 composition, the examiner agrees with Applicant's arguments and has subsequently dropped the rejections over the instant claims 35 – 37.

NEW REJECTIONS:

The following is a list of new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 – 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising hydroxycitric acid together with a well-defined and specific number of cation combinations, such as calcium, potassium, or sodium, **in a specified amount**, does not reasonably provide enablement for a composition comprising hydroxycitric acid together calcium, potassium, or sodium in any amount as set forth in claim 28. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The examiner respectfully asserts that the instant application teaches very specific compositions. Specifically, as set forth in the instant disclosure, the instant specification provides enablement for a composition comprising hydroxycitric acid together with calcium, potassium, or sodium in a specified amount and submits that said composition is unexpectedly odor free, non-hygroscopic, and tasteless. The unexpected results stem from a double (or triple salt) of hydroxycitric acid wherein said calcium, potassium, or sodium cations are present in specific amounts.

Double Patenting

Art Unit: 1615

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 that states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 25-26, 28-30, 42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-5, 7-9, 12 of copending Application No. 11/209429 ('429). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. '429 claims compositions comprising (1) hydroxycitric acid in the amount of approximately 55 – 65%, calcium in an amount of either 14 – 26% by weight or 9 – 13% by weight (depending on how the percentage by weight is calculated), potassium in an amount of either 24 – 40% by weight or 9-20% by weight, or 14 – 18% by weight (depending on how the percentage by weight is calculated), or sodium in an amount of either 14 – 24% by weight or 5 - 12% by weight (depending on how the percentage by weight is calculated), and mixtures thereof. The above limitations are the same ones as set forth in the instant claims 25-26, 28-30.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as

Art Unit: 1615

to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-32, 38-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6, 10-11, 13-36 of copending Application No. 11/209429 ('429).

Although the conflicting claims are not identical, they are not patentably distinct from each other because '429 claims compositions comprising (1) hydroxycitric acid in the amount of approximately 40-65%, calcium in an amount of either 14 – 26% by weight or 9 – 13% by weight (depending on how the percentage by weight is calculated), potassium in an amount of either 24 – 40% by weight or, 9-20% by weight, or 14 – 18% by weight (depending on how the percentage by weight is calculated), or sodium in an amount of either 14 – 24% by weight or 5 - 12% by weight (depending on how the percentage by weight is calculated), and

Art Unit: 1615

mixtures thereof. Like the instant claim set, the composition claimed by '429 can be used as a food product and is suitable for reducing body weight.

Because '429 claims a food product comprising hydroxycitric acid, calcium, and potassium or sodium, and claims that said product can be used to reduce body weight (claim 15, 26, 28), the examiner respectfully suggests that one of ordinary skill in the art at the time the invention was made would have the requisite motivation to claim a food composition comprising hydroxycitric acid, calcium, potassium, or sodium as well as a method of using said composition to reduce body weight. The expected result of such a combination would be an effective weight reducing food composition. As such, given the claims of '429, one of ordinary skill in the art at the time the invention was made would have the motivation to claim a food composition comprising hydroxycitric acid, calcium, potassium, or sodium as well as a method of using said composition to reduce body weight.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

Art Unit: 1615

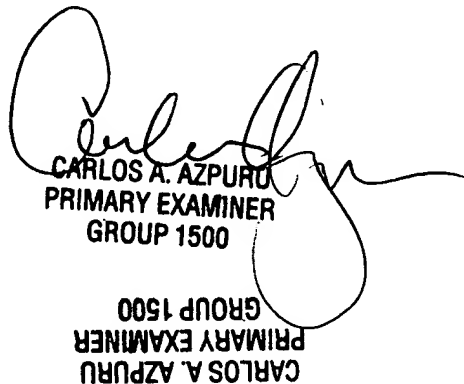
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615



8/2/06



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500